2nd Annual
QUALITY ASSURANCE IN DEVICE AND DIAGNOSTIC MANUFACTURING

Managing Internal Quality Assurance Processes in an Evolving Regulatory Environment, Focusing on Revisions to Medical Device Directives, Utilization of UDIs, and Interactions with Notified Bodies, as well as the use of CAPA in Device & Diagnostic Manufacturing

PROGRAM OVERVIEW
Throughout Europe, medical device and diagnostic manufacturers are being challenged with maintaining compliance within an evolving regulatory environment, where meeting quality assurance standards is becoming increasingly difficult. Recent and ongoing revisions to the Medical Device Directives, focused on increased quality standards, along with the ongoing implementation of Unique Device Identification (UDI) are also causing difficulties for this highly dynamic industry. In a setting where maintaining rigorous quality assurance of all products is of the utmost importance, changes in regulation and procedure are critical and must be executed with precision and understood fully. The 2nd Annual Q1 Quality Assurance in Device & Diagnostic Manufacturing conference will address these issues as well as many other challenges that organizations currently need to address.

In addition to changes to the MDD and UDI requirements, device manufacturers are also working to augment quality assurance standards throughout facilities while also working under pressure to reduce costs and streamline operations. As a result, the use of Corrective Actions and Preventative Actions are becoming an increasingly common tool for today’s manufacturer. In tandem with the changes that CAPA programs build into quality assurance programs are changes to the internal management of quality processes and standard operating procedures. Learning from leading QA executives from throughout the medical device and diagnostic industries will enable participants a well-rounded understanding and perspective on these critical issues.

With presenters bringing perspectives from not only the industry side, but also regulatory perspectives from Notified Bodies, Competent Authorities and the European Commission, this program will answer the many questions and issues that the industry faces today. As with all Q1 conferences, the attendance will be strictly controlled to ensure a limited number of solution providing participants against a higher number of industry representatives, enabling frank discussion and debate on contentious and sensitive issues.

DISTINGUISHED PRESENTERS INCLUDE:

Rainer Voelksen
VP International Regulatory Affairs
EDWARDS LIFESCIENCES
Co-chair European Advisory Committee RAPS

Gert Bos
Head of Regulatory and Clinical Affairs, Medical Devices
BSI GROUP
President
TEAM NB

Jenny Gough
GS1 Specialist
MÖNLYCKE HEALTHCARE

Egon Amann
Director Auditing & Quality System Projects
SIEMENS HEALTHCARE DIAGNOSTICS PRODUCTS

Boris Lux
Head of Regulatory Affairs & Quality Assurance
JENAVALVE TECHNOLOGY

Jomuna Choudhuri
Program Manager, Medical Software Certification
VDE TESTING AND CERTIFICATION INSTITUTE

Géraldine Lissalde-Bonnet
Public Policy Manager
GS1 GLOBAL OFFICE

Kathleen Gallagher
VP Regulatory Affairs & Quality Assurance
DEVICOR MEDICAL PRODUCTS

Holger Most

Regulatory Affairs Leader EMEA
GE HEALTHCARE

Daniel Shoukier
Global Director Regulatory Affairs
BIOSENSORS INTERNATIONAL

Maite Llacer
Director Quality Assurance Compliance
EMEA

EDWARDS LIFESCIENCES

Sabine Ohse
Head of Medical Devices Certification
BSI GROUP DEUTSCHLAND

Johann Harer
Head of Quality Management & Regulatory Affairs
ROCHE DIAGNOSTICS

Stefanie Leschonsky
Manager Quality
ABBOTT DIAGNOSTICS DIVISION

Caroline Bourguignon
Associate Director, Project Management & Quality Assurance
EXONHIT

Michael Schäfer
Director Regulatory Affairs and Quality Assurance
TELEFLEX

Karl Siemoneit
Director, UK/Germany Supply Chain QA
ABBOTT DIAGNOSTICS DIVISION

Thomas Krespach
Quality Assurance Manager Surveillance
GAMBRO DIALYSATOREN
8:30 REGISTRATION & WELCOME COFFEE

9:30 ADDRESSING THE IMPACT OF MDD REVISION ON QUALITY ASSURANCE OPERATIONS
Over the course of the past several months the European Medical Device Directive has been undergoing a thorough revision to better conform with the current healthcare and industry environment. Directives 90/385/EEC on active implantable medical devices, 93/42/EC concerning medical devices and 98/79/EC on in vitro diagnostic medical devices have been updated with the objective of increasing the level of safety for patients, users, and society with rapidly evolving medical technology. While this revision brings many opportunities for patients to be better cared for after high quality and regulated products, it also implies restructuring and implementation strategies for quality teams to meet compliance with the new directives as soon as possible. Recognizing the impact that the release of revised MDD has on quality operations and challenges in complying with new regulations will assist quality teams in developing efficient implementation strategies.

• Enhancement of the MDD scope: new regulated areas
• Centralizing vigilance and market surveillance
• Central registration of devices

Rainer Voelksen, VP International Regulatory Affairs
BSI GROUP, Co-chair European Advisory Committee, RAPS

10:15 EXAMINING CHANGES TO NOTIFIED BODY SUPERVISION AND INSPECTIONS FURTHER TO MDD REVISION
A number of challenges and issues in working with European Notified bodies have been highlighted in the past years, notably in terms of transparency, costs, and delays of inspections from one notified body to another. Further to the revised MDD, the overall notified body framework in Europe has changed and evolved towards a more uniformed and consistent process supervised by a centralized European oversight body. All notified bodies will need to align with the revised MDD in order to continue to operate. Although it is important for device and diagnostic corporations to understand these changes, the impact on quality operations resides mainly in the increasing and reinforcing of notified body audits in manufacturing plants and inspection of processes implementing new scrutiny and areas of examination.

• Standardization of practices and conformity assessments
• Implementation of a centralized European body
• Increasing and standardizing audit approach
• Nominating a qualified person as referent in the collaboration with NBs

Gert Bos, Head of Regulatory and Clinical Affairs, Medical Devices
BSI GROUP, President, TEAM NB

11:00 COFFEE & NETWORKING BREAK

11:15 PANEL DISCUSSION: ENABLING EFFICIENT COLLABORATIONS BETWEEN NOTIFIED BODIES & QUALITY TEAMS
Device and diagnostic manufacturers looking to secure European market access must comply with requirements not only from national health authorities but also from notified bodies with which it is essential that quality executives understand how to cooperate. From selecting the most appropriate notified body to work with to efficient communication to ensure clearance in registration, document control or system verification, the overall collaboration between both parties can be challenging. Reviewing key strategies to secure efficient cooperation with European notified bodies will assist in the successful implementation of strategies.

• Selection criteria for European Notified Bodies
• Planning the collaboration and proactive communication
• Addressing registration and how to accelerate processes
• Obtaining the CE mark in a time efficient manner

Stefanie Leschonsky, Manager Quality
ABBOTT DIAGNOSTICS

Holger Most, Regulatory Affairs Leader EMEA
GE HEALTHCARE

Sabile Oshe, Head of Medical Devices Certification
BSI GROUP DEUTSCHLAND

12:00 CLARIFYING AND IMPLEMENTING ISO 13485:2012 AND EN ISO 14971 REVISION
Amongst the different regulations and requirements that device and diagnostic manufacturers must comply with, two international standards have recently been updated, leading quality teams towards rethinking of current processes and rephrasing new ones. Both ISOs 13485 and 14971 address management processes to maintain a high level of quality in the device life-cycle and have been strengthened to focus on ever more product risk mitigation, examining the underlying drivers of these updates and specific areas of change will ensure both revised standards are understood and met.

• ISO 13485 deviations and revision of annexes Z
• Overview of update ISO 13485:2012
• Aligning compliance to ISOs and to MDD
• Emphasizing hazard mitigation and minimizing residual risks

Holger Most, Regulatory Affairs Leader EMEA, GE HEALTHCARE

12:45 LUNCHEON FOR ALL SPEAKERS, SPONSORS & ATTENDEES

1:45 IEC 62304: IMPACT ON MEDICAL DEVICE SOFTWARE COMPLIANCE
As medical device and diagnostic technologies have evolved and continued to increase in complexity over the course of the past several years, so has the software included in these highly complex devices. IEC 62304 provides a standard in the design and development of software medical devices and assists quality executives in the implementation of a risk management plan throughout the device life cycle. The revision of this standard has enhanced product safety and risk mitigation plans, resulting in challenges to redesign processes and implement new requirements in accordance with the revised IEC 62304. In addition to the specific areas of change, the revision will certainly shed light on how to meet new compliance requirements.

• Defining medical device software and relevant classification in the IEC 62304 standard
• Understanding the revision and specific areas of change
• From IEC 62304 to IEC TR 80002-2

Jomuna Choudhuri, Program Manager, Medical Software Certification
VDE TESTING AND CERTIFICATION INSTITUTE

2:30 UNIQUE DEVICE IDENTIFICATION: OVERVIEW OF US & EU REGULATORY REQUIREMENTS
From better handling of product recalls to enhanced traceability, Europe as well as the U.S. are now requiring that manufacturers implement a Unique Device Identification (UDI) for all device and diagnostic products. The FDA and the EU Commission have worked on regulations and implementation guidelines to assist manufacturers in the first steps towards compliance. Through this overview on the purpose of UDI and implementation strategies, Quality executives will have a better understanding of how to meet requirements from US and EU regulators in a timely manner.

• Overview of US and EU requirements
• Understanding UDI compliance in the US and EU
• Implementation strategies & cost considerations

Géraldine Lissalde-Bonnet, Public Policy Manager
GS1 GLOBAL OFFICE

3:15 COFFEE & NETWORKING BREAK

3:30 BEST PRACTICES IN DEVELOPING & EXECUTING A PROFICIENT UDI STRATEGY
With the forthcoming implementation of UDI regulations in the U.S. and in Europe, device and diagnostic manufacturers must modify internal strategies to meet new requirements. Redesigning processes and putting them in practice without slowing internal operations is very challenging and requires that teams come together to ensure that all understand and implement new requirements. Learning from a peer’s experience on how to best develop an internal UDI strategy and bring it to life, will shed light on practical dos and don’ts to ensure a successful implementation.

• UDI impact on different teams
• Selecting the most appropriate type of coding
• Developing a realistic budget plan
• First steps with UDI

Jenny Gough, GS1 Specialist
MOLNYCKE HEALTHCARE

4:15 UNDERSTANDING EVOLVING REGULATIONS OUTSIDE OF WESTERN EUROPE: FOCUS ON CHINA
Although many medical device and diagnostic manufacturers are conforming with the regulatory framework and quality standards within the Western European regulatory framework, challenges continue to evolve in many other countries worldwide, notably in China where regulations are not as clear. As many manufacturers look to this market to reduce their operating costs and take advantage of highly skilled labor forces at reduced rates, it is essential to fully appreciate the regulatory requirements and quality standards in place. Through this presentation, attendees will gain a more solid understanding of the regulatory frameworks in this exciting and evolving market.

• SFDA device and diagnostic classification in China
• Product registration process
• Appointment of a legal agent and after sales agent
• Chinese QMS specific requirements in line with ISO 13485 & FDA GMP

Kathleen Gallagher, VP Regulatory Affairs & Quality Assurance
DEVICOR MEDICAL PRODUCTS

5:00 DEVELOPING AND IMPLEMENTING A ROBUST VALIDATION PROCESS
When manufacturing medical devices and diagnostics, the necessity of complying is pivotal to ensure all products are manufactured in the same way, presenting the same level of quality and performance. Quality executives must develop a validation process, enabling the verification and confirmation of consistency in medical product manufacturing, as well as providing evidence of the capability of the manufacturer to continually produce a product. Recognizing challenges in the development and implementation of a robust validation strategy will enhance quality teams’ understanding of how to set the most appropriate and efficient process within their corporation.

• Bringing together all relevant regulations
• Addressing validation process in the standard operating procedure
• Recognizing challenges in documentation
• Revalidating in a time effective manner
• Addressing validation of software controlled processes

Johann Harer, Head of Quality Management & Regulatory Affairs
ROCHE DIAGNOSTICS

5:45 CLOSING REMARKS & DAY ONE CONCLUSION
8:00 REGISTRATION & COFFEE

8:30 DESIGNING AN EFFECTIVE QUALITY MANAGEMENT SYSTEM WITH LIMITED RESOURCES
Putting together an efficient strategy to manage and monitor quality systems is always a critical task for device and diagnostic manufacturers, even more so when resources are limited. With teams being downsized and budgets restricted, it is increasingly challenging to find strategies to operate in a timely manner and within limits. Addressing the development and implementation of cost effective QMS will ensure quality executives better plan and handle internal processes.

- Working with reduced or small teams
- Overcoming budget restrictions without slowing operations
- Strategies for good system managing and monitoring

Caroline Bourguignon, Associate Director, Project Management & QA EXHONIT

9:15 EMPHASIZING RISK MANAGEMENT IN QUALITY SYSTEMS
Throughout the utilization of a device or diagnostic product, patients are exposed to potential risks that must be taken into account and minimized by manufacturers. Risk management is in the spotlight more than ever and its use is no more limited to product development only. Strengthening existing risk management processes and developing new mitigation strategies will ensure patient safety is of top priority in quality systems.

- Real-life examples of value adding Risk Management applications
- ISO 14971: opportunities and limitations
- Resigning risk management strategies

Michael Schäfer, Director Regulatory Affairs and Quality Assurance TELEFLEX

10:00 COFFEE & NETWORKING BREAK

10:15 SUCCESSFULLY MANAGING AUDITS IN EUROPEAN DIAGNOSTICS MANUFACTURING PLANTS
Implementing and maintaining Quality Management Systems (QMS) according to ISO 13485, ISO 9001 and the FDA 820 requires the establishment of procedures for quality audits. The organization shall conduct internal audits at planned intervals to determine whether the QMS complies with the essential requirements of international standards, to the QMS requirements established by the organization, and is effectively implemented and maintained. Internal audits need to be planned, whereby the status and the importance of the processes and areas to be audited as well as previous internal audit results need to be taken into consideration. The internal audit process can be prone to Notified Body and other third party inspections and thus constitutes a critical element in the context of conformity assessment by competent authorities and other regulatory bodies. Through this practical case study quality executives will have a better grasp of how to handle internal quality audits and use their outcome to improve and strengthen the organization.

- Implementing internal audits and correcting non-conformities
- Utilizing internal audit findings to maintain and improve compliance
- Sharing knowledge and experiences within the device corporation
- Considering appropriate behavior and communication with inspectors
- Audits as a management tool for continuous improvement

Egon Amann, Director Auditing & Quality System Projects SIEMENS HEALTHCARE DIAGNOSTICS PRODUCTS

11:00 BEST PRACTICES IN DEVELOPING AN EFFICIENT DOCUMENT CONTROL SYSTEM
The increasing requirements for medical device documentation can now be managed by a software environment, including a file archiving system as well as a complex document developing tool. Access to such a system and the ability to utilize the support of international standards, based on FDA 820 and ISO 13485 requires the establishment of procedures for quality audits. The organization shall conduct internal audits at planned intervals to determine whether the QMS complies with the essential requirements of international standards, to the QMS requirements established by the organization, and is effectively implemented and maintained. Internal audits need to be planned, whereby the status and the importance of the processes and areas to be audited as well as previous internal audit results need to be taken into consideration. The internal audit process can be prone to Notified Body and other third party inspections and thus constitutes a critical element in the context of conformity assessment by competent authorities and other regulatory bodies. Through this practical case study quality executives will have a better grasp of how to handle internal quality audits and use their outcome to improve and strengthen the organization.

- Evolving from regular file management systems to WSS
- Ensuring a compliant, safe and efficient sharing process
- Overview of practical WSS features

Boris Lux, Head of Regulatory Affairs & Quality Assurance JENVALVE TECHNOLOGY

11:45 MAXIMIZING QUALITY THROUGH CORRECTIVE AND PREVENTIVE ACTIONS
While not mandatory, Corrective Actions and Preventive Actions (CAPA) enable device manufacturers’ overall commitment to continuously improve quality system management and more specifically, risk mitigation. Developing a CAPA strategy or updating existing CAPA processes, as well as identifying and prioritizing key KPIs that will be measured and audited by the QMS will be a challenging and time consuming responsibility for quality teams. Examining peers’ strategies in CAPA development, implementation and successful results will ensure a stronger understanding of guidelines and underlying benefits.

- Determining the need for CAPA
- Developing a tailored CAPA strategy without slowing down operations
- Utilizing existing guidance on CAPA
- Managing CAPA results in product or process design changes

Stefanie Leschonsky, Manager Quality ABBOTT DIAGNOSTICS DIVISION

12:30 LUNCHEON FOR SPEAKERS, SPONSORS & ATTENDEES

1:30 ELABELING IN EUROPE: BENEFITS AND IMPLEMENTATION STRATEGIES
In September 2011, the European Commission issued the long awaited Electronic Labeling for Medical Devices draft and providing guidance and clarity to the industry related to enhanced labeling requirements. After decades of providing labels and instructions for use in paper format, with the necessity of having all information translated into 23 European languages as well as environmental and shipment challenges, device manufacturers can now provide this documentation in an electronic format. While benefits of labeling are numerous, quality teams must ensure they fully understand EU requirements to secure a cost and time effective implementation.

- Update to MEDDEV 2007/47/CE and adoption of 207/2012
- Implementation timeline and strategies

Daniel Shoukier, Global Director Regulatory Affairs BIOSENSORS INTERNATIONAL

2:15 QUALITY ASSURANCE OF EXTERNAL SUPPLIERS: BEST PRACTICES AND RISK MANAGEMENT STRATEGIES
Complex supply chains and contract manufacturing is a reality in the development, manufacturing and distribution of devices in a global environment. When contracting and collaborating with external suppliers, device and diagnostic quality executives need to ensure adequate control of purchased products and services. Various strategies exist to verify the overall compliance of suppliers and furthermore set up an appropriate collaboration between both parties, securing efficient business cooperation. Examining means of supplier quality control will assist quality teams in achieving successful and compliant collaborations.

- Addressing liability of the finished product
- Selecting the right partners
- Auditing product supplier manufacturing plants
- Concerns in importing excipients from non-European countries

Karl Siemonelt, Director, UK/Germany Supply Chain QA ABBOTT DIAGNOSTICS DIVISION

3:00 COFFEE & NETWORKING BREAK

3:15 ACHIEVING VALUABLE POST-MARKET FEEDBACK AND COMPLAINT HANDLING
Once a device or diagnostic is launched onto the market and utilized by patients and hospital staff, quality executives are expected to monitor the performance and effectiveness of the medical product throughout its entire life cycle via customer, user or regulator feedback. Many challenges reside in collecting and properly handling reported information, notably in the definition of responsibilities, classification of the data and implementation of corrective actions. Addressing quality assurance and post-market feedback management and utilization will assist quality teams in establishing or updating a proficient system within their corporation.

- Broadening research, collecting and classifying feedback
- Differentiating complaints from feedback
- Establishing a feedback loop to the quality system
- Emphasizing complainant follow-up, correcting and closing complaints
- Maintaining records

Maite Llacer, Director Quality Assurance Compliance EMEA EDWARDS LIFESCIENCES

4:00 THOROUGHLY MANAGING POST-MARKET QUALITY ASSURANCE
Further to recent cases of product failure and recalls in the device industry, quality of medical products and safety of patients and users are in the spotlight, resulting in enhanced post-market surveillance and tracking requirements from the European Commission and national regulators. Within the scope of post-market activities, quality teams have a large role to play in monitoring, vigilance and maintaining viability of the marketed product all within a highly regulated and evolving setting. Recognizing quality assurance responsibilities in post-market activities will enhance executives’ understanding of how to remain compliant and efficient in marketed product monitoring.

- Remaining abreast of evolving regulations
- Integrating requirements into the overall quality management system
- Addressing Medical Device Reporting (MDR)
- Enabling a performance measurement process
- Product recall: when and how

Thomas Krespach, Quality Assurance Manager Surveillance GAMBRO DIALYSATOREN

4:45 CLOSING REMARKS & CONFERENCE CONCLUSION
WHO SHOULD ATTEND:
Participants in the 2nd Annual Q1 Quality Assurance in Medical Device & Diagnostic Manufacturing conference will include executives from a wide range of corporations currently manufacturing products across the European market, from small to very large organizations operating on a multinational level. With presenters delivering case-studies and panel discussions aimed at high level quality, regulatory and compliance issues, the executives participating in the program will have a strategic role within their organizations. Job functions that will be of the greatest relevance for this program include:

VPs, Directors and Managers of:
- Quality Assurance
- Quality Systems
- Quality Control
- Quality Management
- Quality & Regulatory Affairs
- Quality Compliance
- Operations
- Product Surveillance
- Validation

SPONSORSHIP OPPORTUNITIES:
With a range of sponsorship opportunities available for companies looking to increase their visibility and prominence in this marketplace, Q1 has designed a wide variety of packages and solutions, available to all sizes of budget. The primary focus of any sponsorship package will be of course centering on creating value and interest in products and services, as well as ensuring a high number of networking opportunities. Initial program research has indicated that the following products and services are currently of interest to this target audience:

- Quality Assurance and QMS Consultants
- Systems Consultants
- Global Regulatory Compliance Consultants
- Validation Software & Consultation
- CAPA Software & Consultation Services
- Regulatory Affairs Outsourcing
- Compliance & Quality Training Solutions

PREVIOUS ATTENDEES INCLUDE:
Quality Assurance Manager, AB Analitica
Divisional VP, Quality Assurance, Abbott
Quality Manager, Abbott Diagnostics
Director, Quality ADD, Abbott GmbH & Co
Manager, Compliance & Quality Systems, Abbott Vascular
Manager, Quality & Regulatory, AGFA Healthcare
VP Quality Management, AstraTech AB
VP Quality & Regulatory, Atos Medical AB
Regulatory Affairs Manager, Axis-Shield
Quality Systems Manager, Biocompatibles UK, Ltd.
VP Quality Control, BoneSupport AB
Regulatory Affairs Manager, BSI Group
IVD Expert & Auditor, BSI Group
Quality Manager, Cochlear Technology Center
Manager, Quality Assurance, ConvaTec
Director, Corporate Quality Assurance, DiaSorin SpA
Manager, Quality Assurance, DSM Biomedical
Quality Assurance Manager, Elekta
Director, Product Surveillance, Elekta
Quality Manager, F. Hoffman LaRoche
Quality Assurance Manager, Fortimeditx BV
Product Identification Manager, Fresenius Kabi
EMEA Quality Manager, Devices, Hospira UK Ltd
Quality & Compliance Manager, Innogenetics NV
Head, Quality Assurance & Regulatory, JenaValve
VP Global Operations, Leica Microsystems Group
Director, Quality Assurance, Link Medical Research
Director, Quality & Compliance, Maquet Cardiovascular
Head, Regulatory Affairs, Medela AG
Director, Regulatory Affairs & Policy, Medtronic
Quality Assurance Director, neoSurgical Limited
VP Operations, Neorotech sa
Director, Regulatory Compliance, Obtech Medical
Quality Manager, Osstell AB
Head of Quality, Owen Mumford Ltd
Director, Quality & Regulatory, Oxford Immunotec
Director, Quality & Regulatory, Philips Healthcare
Quality & Validation Manager, Ranier Technology
Head of Quality Management, Roche Diagnostics
VP QM, RA & Operations, Sequana Medical
Quality Affairs Director, EMEA, St. Jude Medical
Quality Assurance Manager, St. Jude Medical
Sterility Assurance Specialist, Stryker
Manager, QMS, Sysmex Europe
QA & Regulatory Director, Systagenix
Director, QA, Teleflex Medical
Quality Systems Manager, Terumo Europe NV
VP Quality Assurance & Regulatory, Zimmer

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